polymer ***balloon*** composed of a micro-composite material including a polymer matrix component and a polymer fibril component having micro-fibers oriented substantially parallel or diagonally to the longitudinal axis of the balloon.

Independent claim 31 of the present invention is directed to an inflatable medical ***balloon*** which is composed of a semi-compliant matrix material having a plurality of cores therethrough wherein the cores are composed of one or more materials which are characterized as being stronger than the matrix material when the one or more materials are oriented in the direction of the longitudinal axis.

LeVeen et al., US 4,448,195

LeVeen et al. teaches a one piece balloon catheter which is formed by blow molding an elongated polyurethane tube so that ***one section of the tube has a thinned cross sectional balloon*** area between the distal end of the tube which is sealed and its open proximal end. The balloon portion which is positioned adjacent the distal end has a thinner cross sectional area which allows a balloon to be formed if a fluid is introduced into the catheter. See Abstract.

Applicants submit that LeVeen et al. describe a reinforcement netting structure which may be woven glass fibers or a braided shell wire reinforcement which ***is placed at the beginning and end of the thinned portion of the balloon section, but not at the center.*** See col. 2, lines 45-52, Fig. 5 and col. 3, lines 29-36. As can be seen from the description and from the figures, there is no reinforcement structure where the central balloon portion is. LeVeen et al. actually teach a balloon portion which is thinner such that the balloon can be formed when inflation fluid is introduced. Because LeVeen et al. teach reinforcement only of the tubing on either side of the balloon and not reinforcement of the balloon portion itself, we submit that LeVeen et al. actually teach away from reinforcing the balloon portion.

Zdrahala, US 5156785

Zdrahala describes extruded catheters and other flexible plastic ***tubing*** may be manufactured with improved rotational and/or longitudinal stiffness, compared with catheters made of more conventional plastics. A tubing of liquid crystal polymer plastic-containing

material may be extruded through a tube extrusion die while rotating the inner and outer die walls to provide circumferential shear to the extruded tube. Thus the liquid crystal polymer is oriented in a helical manner to provide improved properties, including greater rotational stiffness.

Zdrahala is discussed in detail in the last response mailed August 26, 2002.

Applicants assert that LeVeen et al. do not teach that the balloon portion of a single piece balloon catheter can be reinforced, but rather the tubing on either end of the balloon catheter. Zdrahala et al. do not suggest employing the liquid crystal polymer plastic-containing material to make a balloon, but only tubing.

Therefore, combining Zdrahala with LeVeen et al. does not suggest that a polymer having a fibril component could be employed to form a balloon. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-8, 12-26, 31, 33 and 36 as being unpatentable over LeVeen et al. (US 4,448,195) in view of Zdrahala.

Claims 9-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over LeVeen et al. in view of Zdrahala as applied to claims 1-8, 12-26, 31, 33 and 36 above, and further in view of Cozewith et al.

Cozewith et al., US 5733980

Cozewith et al. describes block polymers containing both crystalline and elastomeric blocks, the block copolymer having an A block and a B block. Also disclosed is a process for manufacture of the block copolymers and methods for coupling the block copolymers. Coupled block copolymers are useful as thermoplastic elastomers exhibiting physical properties approaching those of crosslinked EP or EPDM elastomers, but showing thermal processability after coupling. The block copolymers may also be used as a lubricant or fuel additive, as a plastics blend component, in bitumen blends, as a component in hot melt adhesives and as a component of roof sheeting compounds.

That the block copolymers may be employed in plastics blending for impact modification of thermoplastics, i.e. rubber/plastic blend compositions. See col. 14, lines 10-32.

LeVeen et al. and Zdrahala are discussed above. As LeVeen et al. describe reinforcing the part of the balloon catheter, other than the balloon itself, and Zdrahala describes tubing and not balloons, combining Cozewith et al. with either LeVeen et al. and/or Zdrahala would not lead one of ordinary skill in the art to the balloons according to the present invention. Independent claim 1 is patentable for the reasons presented above. Claims 9-11 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable. Applicants therefore respectfully request withdrawal of the rejection of claims 9-11 under 35 U.S.C. §103(a) as being unpatentable over LeVeen et al. in view of Zdrahala as applied to claims 1-8, 12-26, 31, 33 and 36 above, and further in view of Cozewith et al.

Claims 32 and 34-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over LeVeen et al. in view of Zdrahala as applied to claims 1-8, 12-25, 31, 33 and 36 above, and further in view of Jorgensen.

Jorgensen, US 5,647,848

Jorgensen describes an improved dilation balloon for securement to a catheter. The balloon includes an elastomeric skin having a constraining structure formed of fibers which is ***affixed thereto***. The constraining structure allows radial expansion between an uninflated diameter $D_{defl.}$ and an inflated diameter $D_{infl.}$. Jorgensen was discussed in detail in the Office Action mailed August 26, 2002.

The balloons of the present invention in contrast to those of Jorgensen et al., are formed by mixing fibrils with the matrix material in a molten state. Thus, the fibrils are dispersed throughout the matrix material, and do not form a constraining structure which is affixed to the balloon as described in Jorgensen et al.

In any case, as LeVeen et al. describes reinforcing balloon catheters, but does not describe reinforcing the actual balloon part of the balloon catheter, and Zdrahala describes tubing and not balloons, combining the constrained structure of Jorgensen et al. with either LeVeen et al. and/or Zdrahala does not lead one of ordinary skill in the art to a balloon as described and claimed in the present invention.

Independent claim 31 is patentable for the reasons presented above. Claims 32 and 34-35 depend from claim 31 and are patentable for at least the reasons that claim 31 is

patentable. Applicants respectfully request withdrawal of the rejection of claims 32 and 34-35 under 35 U.S.C. §103(a) as being unpatentable over LeVeen et al. in view of Zdrahala as applied to claims 1-8, 12-25, 31, 33 and 36 above, and further in view of Jorgensen.

CONCLUSION

Claims 1-26 and 31-36 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing arguments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 21, 2003

By: _____
James M. Urzedowski
Registration No.: 48596

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
JMU/tas
f:\wpwork\lrl\09503us_amd_20021223.doc